PROCESS VERIFIED PROGRAMS (PVP)

Purpose

This instruction provides guidelines and criteria to be used for objective evaluation of agricultural products quality systems programs submitted for approval and monitored by the Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review, and Compliance (ARC) Branch.

Scope

The provisions of this document apply to livestock, meat, and agricultural products marketing programs submitted to the LS Program for verification and monitoring. It is limited to programs or portions of programs where process verified points are supported by a documented quality management system. The extent of controls included in these programs may include all phases of production and marketing from genetic development through retail distribution, or any portion as described in the scope of the submitted program

Policy

Policy and procedures for submission of programs for approval and monitoring by AMS are outlined in Instruction ARC 1000 Quality Systems Verification Program, General Policies and Procedures For All Programs.

Requirements

Programs submitted in writing to the LS Program will be approved when it is determined that they meet the criteria shown below and the program has successfully passed an onsite audit conducted according to procedures outlined in ARC Instruction 1000.

1. Management Responsibilities

1.1 Programs must designate a person responsible for ensuring all program requirements.

1.2 There must be a person designated with the authority to act on behalf of the organization at all locations where program activities are conducted.

1.3 An organizational chart or similar document listing all persons assigned to positions within the program must be available for review.

1.4 All persons listed must have their authority and responsibilities outlined in an auditable method.

1.5 A program representative must demonstrate the controls used to control the accuracy of claims of subsequent distributors of products of approved programs.

2. Quality System

2.1 A quality system must be established, documented and maintained which assures that products conform to specified requirements.

2.2 Programs must have procedures that support the stated quality policy.

2.3 Quality system procedures must be effectively implemented at all levels.

3. Contract Review

3.1 There must be established documented procedures to review contracts.

3.2 These documented procedures must include provisions for verifying verbal orders, contracts, agreements, or amendments.

3.3 There must be procedures to review all contracts to assure the supplier is capable of meeting all contract or accepted order requirements.

3.4 A record of all contract reviews must be maintained.

4. Document and Data Control

4.1 The associated program shall maintain records demonstrating compliance with program requirements.

4.2 The associated program must include a statement of the objectives of the process verified program.

4.3 The program shall prepare and maintain a program manual that contains, at a minimum:
(a) the names and positions of persons with managerial responsibilities for operation of the process verified program.
(b) a description of the scope of the process verified marketing program.
(c) a description of product, system attributes or process verified points.
(d) written procedures addressing all program requirements.
(e) completed examples of all forms, tags, and labels used to track or demonstrate program compliance.

4.4 The program manual must be controlled and available for review at all associated sites where activities are conducted.

5. Purchasing

5.1 A procedure must be in place to ensure that purchased products conform to specified requirements.

5.2 Procedures must be in place to evaluate and select subcontractors based on their ability to meet the subcontract requirements.

5.3 An acceptable subcontractors list must be maintained along with records on sub-contractors' past performance.

6. Control of Customer Supplied Product

6.1 There must be procedures for evaluating customer supplied product before it is used.

6.2 Procedures to ensure customer supplied product is stored, maintained, and incorporated into program supplies in a controlled manner.

6.3 There must be procedures for recording and reporting damaged, missing or otherwise unsuitable products to the customer who supplied them.

6.4 Procedures for controlling nonconforming customer supplied products and preventing them from being further processed must be documented.

7. Product Identification and Traceability

7.1 The supplier shall develop and maintain written procedures for identifying product either by individual animal numbers or product lot identification unique to the associate process verified program.

7.2 When applicable, animals must be identified with an ear tags or other permanent identification.
7.3 Identification of product must be such that the identification will transfer through all phase of production, from receipt into the program, through production and up to delivery.
7.4 The program must maintain records of all changes of identities.
7.5 The program must record all products as identified.
7.6 Procedures must provide positive traceability of all products from initial acceptance to delivery.

8. Process Control

8.1 Detail procedure for all activities associated with the program must be available for review.
8.2 Detail procedures must be readily available for reference at all points of use through out the program sites.
8.3 Objective criteria for the acceptability of products for further processing and final acceptance must be documented. This must be documented in program manuals at all associated sites where work is performed on program operations.
8.4 Work instructions and product quality control records must prescribe levels of quality through all stages of production.

9. Inspection and Testing

9.1 The program shall establish and maintain procedures for conducting necessary inspections and/or tests to ensure product received comply with all program requirements.
9.2 When required, the program shall establish and maintain procedure for conducting appropriate in-process inspection and / or tests on cattle, carcasses or product to ensure program compliance.
9.3 The program shall develop and maintain procedures for ensuring all program requirements are met prior to final acceptance.
9.4 The program shall develop and maintain procedures for recording results of inspections and tests used to determine or demonstrate program compliance.

10. Control of Inspection, Measuring, and Test Equipment

10.1 There must be procedures established to control, calibrate, and maintain equipment used to verify compliance with specified program requirements.
10.2 The supplier must determine all measurements to be made, the accuracy required and select the appropriate equipment that is capable of the accuracy and precision required.
10.3 All inspection, measuring, and test equipment must be calibrated and adjusted at prescribed intervals or prior to use.
10.4 Calibration and identification records for inspection, measuring and testing equipment must be maintained.

11. Inspection and Test Status

11.1 Documented procedures must clearly define how products are identified for acceptability through each phase of production, handling, packaging, storage, and shipping.
11.2 All nonconforming and conforming product and materials must be positively identified.

12. Control of Nonconforming Product

12.1 There must be procedures established to ensure that nonconforming products are not unintentionally used or distributed.

12.2 Procedures must include identification, evaluation, and segregation processes for nonconforming product.

12.3 The authority for reviewing and determining the disposition of nonconforming product must be defined.

13. Corrective and Preventive Action

13.1 Documented procedures must be established and maintained for implementing corrective and preventive action.

13.2 Controls to ensure that corrective action is taken and that it is effective must be in place.

14. Handling, Storage, Packaging, and Marking

14.1 Procedures for handling and storing product that prevent damage or deterioration must be defined.

14.2 There must be procedures to control packing, packaging, and marking processes to ensure conformance to specified requirements.

15. Control of Quality Records

15.1 A master document list must be available for review.

15.2 The master document list must show the most current issue of all program forms, procedures, and other instructions.

15.3 Procedures must define retention requirements of all documents.

15.4 All documents must be retained for a period of at least one year.

15.5 After initial program review substantive changes of program documentation must be submitted to the LS program for approval prior to implementation.

15.6 Records must be stored in a manner so as to prevent loss, damage, or alteration.

15.7 Records must be easily accessible and readily available.

16. Internal Quality Audits

16.1 The program shall develop and maintain procedure for conducting internal audits of all operations and documentation to ensure all program requirements are met.

16.2 Records of internal audits shall be maintained.

16.3 Results of internal audits shall be reviewed by management and when appropriate, used to improve program's policies and procedures.

17. Training

17.1 The program shall develop and maintain procedures for ensuring all persons with program responsibilities are properly trained in relevant aspects of the program.

17.2 The program must include the criteria for personnel certification.

17.3 The program shall maintain records of persons trained and the scope of the training received.

18. Statistical Techniques

18.1 When statistical methods are used to control product quality or integrity, the basis for those procedures must be clearly defined.

19. Control of Promotional Materials.

19.1 Program procedures for monitoring promotional and advertising material should be developed and submitted as a portion of the overall quality program.

19.2 Programs must be able to document that promotional material accurately represents the process points verified by the USDA.

19.3 When the USDA Shield is used it must be directly linked to the processes verified by the USDA

19.4 The Quality Manual must adequately address the control and oversight of the promotional materials.

20. Customer Satisfaction

20.1 Programs must have written procedures for complying, analyzing, and acting upon information contained in customer feedback data, reflecting, the level of customer satisfaction.

20.2 Programs must have procedures to incorporate customer satisfaction measures into continual improvement efforts.

20.3 There must be procedures for conducting customer satisfaction surveys.

20.4 Programs must have a procedure for retrieving, analyzing, and acting on customer complaint data.

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